90-1925

(1)

Supreme Court, U.S.
FILED
JUN 14 1991
OFFICE OF THE CLERK

IN THE

Supreme Court of The United States

OCTOBER TERM 1991

No.

SURINDAR S. BEDI,
Petitioner,

vs.

UNITED STATES,
Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

PETITION

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QUESTIONS PRESENTED

I. DOES A PHYSICIAN COMMIT THE OFFENSE OF MAKING "FALSE, FICTITIOUS AND FRAUDULENT CLAIMS" TO A UNITED STATES AGENCY TO OBTAIN PAYMENT OF A MEDICARE CLAIM, WHERE HIS STATEMENTS ARE LITERALLY TRUE UNDER MEDICARE'S AMBIGUOUS GUIDELINES, EVEN THOUGH SUCH STATEMENTS MAY BE CALCULATED TO EVADE DENIAL OF PAYMENT?

II. DOES THE GOVERNMENT FAIL TO STATE THE OFFENSE OF CONSPIRACY TO DEFRAUD THE GOVERNMENT WITH FALSE, FICTITIOUS OR FRAUDULENT MEDICARE CLAIMS, WHERE AN INDICTMENT ALLEGES THAT A PHYSICIAN PARTICIPATED IN THE FALSE BILLING OF A "NON-COVERED" MEDICARE SERVICE AS A COVERED SERVICE, AND BY SUBSEQUENT ADMINISTRATIVE RULING THE DEPARTMENT OF HEALTH AND HUMAN SERVICES DEEMS THE "NON-COVERED SERVICE" AS A "COVERED" MEDICARE SERVICE?

PARTIES BELOW

United States of America

Surindar S. Bedi, M.D.*

*Petitioner in this Court

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SURINDAR S. BEDI,
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vs.

UNITED STATES,
Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

SURINDAR S. BEDI, M.D. ("Dr. Bedi") petitions for a Writ of Certiorari to review the decision of the United States Court of Appeal for the Eleventh Circuit, which affirmed the Petitioner's convictions for conspiracy to defraud the government by aiding, abetting or inducing the filing of false, fictitious, or fraudulent Medicare claims.

OPINION BELOW

The decision *sub judice* of the United States Court of Appeal for the Eleventh Circuit is officially reported as *United States of America v. Surindar S. Bedi*, _____F.2d _____ (11th Cir. 1991). This decision is attached herein as Appendix A.

JURISDICTION

On March 18, 1991, a panel decision was filed in the United States Court of Appeal for the Eleventh Circuit, therein affirming the Petitioner's convictions and sentence (Appendix A, *infra*). This Petition for Writ of Certiorari is jurisdictionally proper and timely filed within ninety (90) days of the Eleventh Circuit's decision, in accordance with Rules 10.1 and 13.1 of the Rules of the Supreme Court of the United States, as amended to February 1, 1991.

STATUTORY AND CONSTITUTIONAL PROVISIONS INVOLVED

This Petition involves the Due Process Clause of the United States Constitution and 18 U.S.C. §§ 2, 286 and 287.

STATEMENT OF THE CASE

On May 11, 1989, a 20-count Indictment was filed against Dr. Bedi in the United States District Court for the Middle District of Florida, Tampa Division. Count I alleged conspiracy to defraud the United States Government with respect to Medicare claims, and Counts II through XX alleged making false, fictitious, or fraudulent claims, in violation of 18 U.S.C. §§ 2, 286 and 287.

According to the Indictment, Dr. Bedi operated a clinic called "Heart Helpers, Inc." located in Zephyrhills, Florida, which had provided intravenous treatment with a chemical called EDTA, known as chelation therapy.[1] The scope of the

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[1] As noted by the Supreme Court of Florida in *State Board of Medical Examiners of Florida v. Rogers*, 287 So.2d 937, 938 n. 2 (Fla. 1980), "chelation therapy consists of a series of intravenous injections of a chelating drug, usually disodium ethylenediamine tetraacetic acid

Indictment concerned the administration of chelation therapy treatment to eleven patients who had suffered from arteriosclerosis.[2] It has been recognized that "chelation therapy is widely used as a 'treatment' for arteriosclerosis, though by a definite minority of the medical profession."[3]

The Indictment alleged that "the Defendant, Surindar S. Bedi, knowing that chelation therapy was a *non-covered* Medicare service, would and did cause Heart Helpers, Inc. to falsely b'll the Medicare program by representing chelation therapy as cardiovascular chemotherapy on Medicare health insurance claims forms, which would then be sent off for payment under the provisions of the Medicare program." In addition the Indictment alleged that Dr. Bedi caused his clinic "to submit false claims to the Medicare program, such claims being false as they represented *non-covered* office services provided in conjunction with chelation therapy, as being covered services provided in conjunction with cardiovascular chemotherapy" [Appendix C, *infra*].

On or about July 17, 1989, Dr. Bedi filed a motion to dismiss the Indictment, asserting that the allegations "failed to state facts sufficient to constitute a crime or an offense against

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(hereinafter disodium EDTA, Na2 EDTA, or EDTA). Each injection takes approximately three to four hours to administer, and a normal course of treatment usually involves twenty such injections. The treatments are specifically intended to treat arteriosclerosis (hardening of the arteries), atherosclerosis (deposits on the inner lining of the arteries), and other generalized circulatory deficiencies caused by excess calcium in the circulatory vessels."

[2]During opening argument at trial, the prosecutor stated that the chelation therapy for the eleven patients in question "was given basically to combat arteriosclerosis, hardening of the arteries, narrowing of the arteries" (1 R 8).

[3]*Rogers v. State Board of Medical Examiners*, 371 So.2d 1037, 1040 (Fla. 1st DCA 1979), *affirmed*, 387 So.2d 937 (Fla. 1980).

the United States, and the facts upon which the Indictment was rendered, do not constitute the violation of any statutes that the United States is empowered to act."

The one-week jury trial of the cause took place in Tampa, Florida before the Honorable Ben Krentzman, Senior United States District Judge, from February 1-7, 1990. At the trial, the Government presented testimony from a number of witnesses, including several former employees of the clinic operated by Dr. Bedi in Zephyrhills and New Port Richey, Florida.

Robert Foster, a policy specialist with the federal agency that administered Medicare (the Health Care Financing Administration), testified at trial concerning several sections of the Medicare "Coverage Issues Manual" published by his agency. Foster mentioned that two sections of his agency's manual were titled "Chelation Therapy for Treatment of Artherosclerosis." Foster read section 35-64 from his agency's manual, which provides, "EDTA chelation therapy for artherosclerosis is considered experimental." In addition, Foster also read section 45-20, which notes, "The use of EDTA as a chelating agent to treat artherosclerosis, arteriosclerosis, calcinosis, or similar generalized conditions not listed by the FDA as an approved use is not covered" (1 R 30). However, the Coverage Issues Manual is only distributed to Blue Cross/Blue Shield of Florida, which administers Medicare Part B claims in the State of Florida for the Federal Government.

During 1984, Dr. Daniel Towle, a chiropractor, served as clinical director of Dr. Bedi. According to Dr. Towle, he heard the phrase "cardiovascular chemotherapy" during multiple staff meetings at their office, and learned from Dr. Bedi that they were having difficulty receiving payment from medical for chelation therapy which was being performed in the office, so as an *alternative*, they were using the code for

cardiovascular chemotherapy so that they could receive reimbursement for it. Dr. Towle testified that the CPT code book provided for a number of different types of chemotherapy that were available: "One of them was specifically cardiovascular chemotherapy" (1 R 48-49, 51).

The 1984 chelation therapy treatments were billed to Medicare under the codes 96504 and 96505, which provide: "Chemotherapy injection, intravenous, multiple pre-mixed agents administered by qualified assistant under the supervision of a physician or by a physician by push technique" (1 R 52, 53). And code 96505 is similar to 96504, but is intravenous chemotherapy by the "drip" method. When asked if they are both chemotherapy treatments "for malignancies," Dr. Towle responded that it would be a reasonable assumption (1 R 54).

The Government presented the testimony of prosecution witness Terry Flicker, who was employed as the office manager and medical assistant in Dr. Bedi's medical facility in Zephyrhills from 1983 to 1985 (2 R 175). At the Zephyrhills clinic, the resident supervising physician was Khann H. Cao, M.D., a licensed Florida doctor. (2 R 175). Flicker noted that chelation therapy was regularly given at the clinic. When she first started with Dr. Bedi's clinic, she was told by Dr. Bedi that Medicare would not pay for chelation therapy. Accordingly, the (Medicare) patients paid cash for chelation therapy, as her office would never take assignments from the patients for chelation therapy (2 R 178).

In May and June of 1984 the eleven patients in question were administered chelation therapy with four-hour intravenous injections at the clinic in Zephyrhills, Florida. Each of those eleven patients were treated by Dr. Cao, a Vietnamese native who trained in medicine in Saigon. Dr. Bedi never treated nor consulted with any of the eleven patients who were administered the chelation therapy.

Each of the eleven patients were advised by the clinic in writing that Medicare would not reimburse them for chelation therapy for treatment of arteriosclerosis. Accordingly, these patients paid for the therapy directly to the clinic following treatment. However, at some time in 1984, Dr. Bedi advised Ms. Flicker that chelation therapy could be billed to Medicare as cardiovascular chemotherapy, and to see if Medicare would cover it. Dr. Bedi then asked Ms. Flicker to get the reimbursement code from Medicare for cardiovascular chemotherapy, since if Medicare would cover it, the patients could be reimbursed.

Ms. Flicker was trained in the medical field as a medical assistant, and had attended a chelation workshop in Jacksonville in 1984. According to Ms. Flicker, cardiovascular chemotherapy and chelation therapy were the "exact same treatments":

> "Question: To your mind, was cardiovascular chemotherapy the same thing as chelation therapy?
>
> Answer: Yes, sir.
>
> Question: Who told you that?
>
> Answer: It was the *same exact treatment.*
>
> Question: Okay. But the codes are different?
>
> Answer: Yes, sir.
>
> Question: Do you have any training in the medical field?
>
> Answer: Yes, sir. I am a medical assistant."

Dr. Cao would examine the patients and prescribe chelation therapy for these patients in the charts. Ms. Flicker personally participated in mixing the bottles of solutions which the chelation patients would receive intravenously, consisting of EDTA, sodium potassium chloride, and B-12 vitamins.

Ms. Flicker would also monitor patients, take blood pressures, make a fruit salad for them, and get them drinks. Prior to administration of the chelation therapy, the patients would go through a routine physical, lab tests, x-rays, and an EKG.

Prior to May 1984, Ms. Flicker called the Medicare office in Jacksonville to get the reimbursement code for cardiovascular chemotherapy, and was given the code numbers "96504" and "96505." That information was apparently obtained from the CPT manual used by Medicare, which provides:

> **Chemotherapy Injections**[4]
>
> Procedures 96500-96549 are independent of the patient's office visit. Either may occur independently from the other on any given day, or they may occur sequentially on the same day. Intravenous chemotherapy injections are administered by a physician or by a qualified assistant under supervision of the physician.
>
> Regional (isolation) chemotherapy perfusion should be reported using existing codes describing complex arterial chemotherapy. Placement of the catheter should be reported using the appropriate code from the *cardiovascular* surgery section. Adjunctive procedures such as lymph node dissection, wide local excision and skin grafts should also be identified separately.

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[4]"Chemotherapy" is defined in *Stedman's Medical Dictionary* (25th Edition) as "Treatment of disease by means of chemical substances or drugs." In *Websters New Collegiate Dictionary* it is defined as "the use of chemical agents in the treatment or control of disease."

96500 Chemotherapy injection, intravenous, single premised agent, administered by qualified assistant under supervision of physician or by physician; by push technique

96501 by infusion technique

96504 Chemotherapy injection, intravenous, multiple premixed agents, administered by qualified assistant under supervision of physician or by physician; by push technique

96505 by infusion technique
(emphasis added)

After the eleven patients were administered the intravenous treatments with EDTA, Ms. Flicker reviewed each patient's ledger cards and prepared an insurance claim form and bill for Medicare. After filling out the claim forms, Ms. Flicker took the signature stamp for Dr. Cao and stamped his name on them. According to Ms. Flicker, Dr. Cao (and Dr. Bedi) never saw or reviewed *any* of these claims forms before they were sent to Medicare. All the claims forms for the intravenous therapy were filed by Ms. Flicker on behalf of the eleven patients. On each of the Medicare claims forms, Ms. Flicker noted "coronary artery disease" or "peripheral vascular disease," for which the service of "cardiovascular chemotherapy" was administered. Dr. Cao was in charge of the Zephyrhills clinic, although Ms. Flicker handled and completed all claims forms. Dr. Bedi was infrequently at the Zephryhills clinic.

Dr. Bedi testified at trial that he had attended a meeting of the American Academy of Preventative Medicine in California in February or March of 1984. After that meeting, Dr. Bedi returned to Zephyrhills and mentioned to Ms. Flicker that there was discussion about the problem of Medicare not

paying people for chelation therapy, which he thought was unfair to the patients. Dr. Bedi also told his staff what he learned medically at the conference about chelation therapy, and how effective it was. He advised the employees at the Zephyrhills clinic that in the place of chelation therapy they could use the term cardiovascular chemotherapy for Medicare reimbursement. Most of the insurance companies were paying for chelation therapy, notwithstanding. According to Dr. Bedi, cardiovascular chemotherapy and chelation therapy are the same thing, using the drug EDTA, which is approved by the Food and Drug Administration. Dr. Bedi denied ever expressly directing Ms. Flicker to call the Medicare office in Jacksonville to get the code for "chemotherapy;" Rather, Dr. Bedi mentioned to his employees, after returning from the medical conference in California, that patients elsewhere were receiving reimbursement by designating the treatment as "cardiovascular chemotherapy."

Dr. Bedi also testified that cardiovascular chemotherapy is treating the cardiovascular diseases with chemicals, and that could be with *any* chemicals. According to Dr. Bedi, chelation therapy and cardiovascular chemotherapy are the same treatments, just different designations.

The Government also presented the testimony of Dwayne Carter, who had been a supervisor of the Medicare section for Blue Cross/Blue Shield for five years. According to Carter, chelation therapy is a covered Medicare service only when administered for "emergency treatment for hypercalcemia," "control of ventricular arrhythmia," and "control of heart block secondary to digitalis toxicity." Carter noted that the treatments on the claims forms as submitted in May and June of 1984 for the eleven patients did not fall within these three circumstances. Carter testified that these policies were published in Medicare "NewsNotes," in March/April of 1984 by Blue Cross/Blue Shield of Florida.

According to Carter, it is customary, usual, and habitual for Blue Cross to send those NewsNotes to all doctors with provider numbers. However, the Government presented no evidence that Dr. Bedi did actually receive and review these "NewsNotes" before May and June of 1984, or at any other time.

In addition, Carter testified that chemotherapy was defined "as a treatment for malignant disease,"[5] according to a "Newsnote" dated July 1, 1984.

The defense presented the testimony of Lorraine Molinari, the president of a company that gives seminars and consulting services on the Medicare rules and regulations as far as coding and reimbursement is involved. Previously, Ms. Molinari served as a Medicare professional relations representative between 1982 and 1985 for Blue Cross/Blue Shield of Florida in Miami, and would help physicians' offices with Medicare coding. Based upon her four years as a Medicare representative for Blue Cross/Blue Shield, she was unaware of *any* doctors that would be given the Medicare carrier's manual with coding and services numbers, unless a doctor would actually subscribe to the Federal Registry to get it. Ms. Molinari testified, "I don't know of anybody that subscribed to it besides, you know, attorneys, people like myself. Most physicians that I know of would not subscribe to this."

More importantly, Ms. Molinari was shown the Government exhibits which Carter relied upon above for his

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[5]"Malignant" is defined in *Dorland's Illustrated Medical Dictionary*, 27th Edition (Harcourt, Brace, Janovich, Inc.) as "tending to become progressively worse and to result in death." Similarly, in *Webster's New Collegiate Dictionary* (1973), "malignant" is described as "tending to produce death or deterioration (malaria); tending to infiltrate, matastasize, and terminate fatally."

definitions of treatments and services, and emphasized that these "NewsNotes" were "something that we *never* did give to physicians." (Emphasis added). Ms. Molinari stressed that the Blue Cross and Blue Shield medical policy procedures were "definitely an *internal* policy." When asked whether or not these "NewsNotes" were sent to physicians in the State of Florida, Ms. Molinari stressed: "No. It was never sent. We -- it's something that is strictly internal policy." She also noted that the CPT manual ("Current Procedure Terminology") was put out in part by the American Medical Association, which is a very thick book and never provided to any physicians in Florida during 1984. Ms. Molinari also mentioned that during 1983 and 1984, the procedure codes were all changed, and a new CPT book came out.

As the CPT manuals and "NewsNotes" were typically not available between 1982 and 1986 to doctors, Ms. Molinari stated that doctors would typically rely on seminars given for physicians and their office staff. Most of the time the seminars were geared to the office staff members, representing the physicians' offices.

At trial, the Government presented no evidence indicating that Dr. Bedi's clinic had not actually provided the intravenous EDTA treatments as indicated on the subject claims forms in May and June of 1984. Nor did the Government dispute the fact that the eleven patients were being treated for arteriosclerosis, as noted by the entries for "coronary artery disease" and "peripheral vascular disease" on the Medicare claims forms. Similarly, the Government presented no evidence at trial that the intravenous chemical treatments with EDTA given to the eleven patients in May and June of 1984 was *not* literally "cardiovascular chemotherapy" for coronary artery disease. Nor did the Government present any evidence indicating that cardiovascular chemotherapy was a non-covered expense for treatment of arteriosclerosis.

At the conclusion of the one-week trial, the jury returned a verdict finding Dr. Bedi guilty of all twenty counts of the Indictment. Judge Krentzman thereafter imposed a five-year sentence of incarceration for Dr. Bedi. [Appendix "A", *infra*]

Subsequently, Dr. Bedi filed a timely Notice of Appeal from his convictions and sentence to the United States Court of Appeal for the Eleventh Circuit. On March 18, 1991, the Eleventh Circuit affirmed the convictions and sentences. [Appendix "B", *infra*]

REASONS FOR GRANTING THE WRIT

I. THE EVIDENCE WAS INSUFFICIENT AS A MATTER OF LAW TO SUSTAIN PETITIONER'S CONVICTIONS FOR CONSPIRACY AND FILING FALSE MEDICARE CLAIMS, AS THE USE BY PETITIONER'S MEDICAL CLINIC OF THE PARTICULAR DESIGNATIONS AND CODES WERE LITERALLY TRUE AND CORRECT BY DEFINITION, AND THE OFFENSE OF MAKING FALSE STATEMENTS TO FEDERAL OFFICIALS CANNOT BE INVOKED WHEN AN EVASIVE STATEMENT IS LITERALLY TRUE.

Dr. Bedi was convicted of violation of 18 U.S.C. Sections 2, 286 and 287. Those sections provides that it is an offense for one to knowingly and willfully aid, abet or induce the presentation of a false, fictitious or fraudulent claim to a department or agency of the United States government, and for conspiring with others to defraud the government by obtaining or aiding the payment of any false, fictitious or fraudulent claim.

"A unambiguous answer literally true cannot be the subject of a perjury or false statement conviction even if intended to mislead." *United States v. Williams*, 536 F.2d 1202, 1205 (7th Cir,. 1976); *Bronston v. United States*, 409 U.S. 235, 93 S.Ct. 595, 34 L.Ed.2d 568 (1973). "[I]f the defendant's statements were 'literally true within the context of the questions asked, even if misleading by implication or omission,' he must be acquitted." *United States v. Kehoe*, 562 F.2d 65, 68 (1st Cir., 1977); *Bronston*, 409 U.S. at 361-362. In *Bronston*, this Court stressed that a "literally true answer," even though unresponsive or "shrewdly calculated to evade," cannot form the predicate for a conviction for making a false statement. *See also: United States v. Sainz*, 772 F.2d 559, 563 (9th Cir., 1985). Thus, in *Bronston* this Court

required that defendant's answers be "literally false" to sustain a conviction, and the offense of making a false statement "is not violated when a witness gives an evasive, nonresponsive but literally true answer, even if the answer is intentionally misleading and arguably false by negative implication." *United States v. Abrams*, 568 F.2d 411, 422 (5th Cir., 1978).

Dr. Bedi moved for a judgment of acquittal at the conclusion of the Government's case in chief and at the end of trial, maintaining that the evidence was insufficient to establish guilt.

The evidence presented at trial, viewed in the light most favorable to the Government with all inferences therefrom, shows as follows: That Dr. Cao and Ms. Flicker had provided medical and therapeutic services to the eleven (11) patients in question, including physical examinations, diagnostic testings and intravenous therapy for arteriosclerosis with the EDTA chemical. Ms. Flicker, the office manager and medical assistant who testified as the main prosecution witness for the Government, stated that she had filled out all of the Medicare claims forms in question in May and June of 1984, indicating that these patients had been administered cardiovascular chemotherapy for treatment of coronary artery disease. Dr. Bedi was aware that chelation therapy was generally a non-covered service per Medicare guidelines, and advised Ms. Flicker, Dr. Cao and others to designate the intraveneous treatments as cardiovascular chemotherapy so that theie patients could receive reimbursement from Medicare. As the clinic did not accept assignment of Medicare benefits, reimbursements would be made *directly* to the eleven patients and not the clinic or Dr. Bedi. After Dr. Bedi advised Ms. Flicker to call the Medicare office in Jacksonville for a code for "cardiovascular chemotherapy," Mr. Flicker called that office and received the codes numbered 96504 and 96505. Ms. Flicker testified for the Government that cardiovascular chemotherapy and chelation therapy were the "same exact treatment," but the codes were merely different.

Notwithstanding, it was undisputed at trial that each of the eleven patients in question did suffer from arteriosclerosis, generically known as coronary artery disease, as truthfully indicated on the subject Medicare claims forms submitted by Ms. Flicker. Similarly, the Government presented no evidence at trial that the intravenous administration of EDTA to the eleven patients *did not* medically constitute "cardiovascular chemotherapy."[6] Thus, those statements made in Ms. Flicker's Medicare claims forms in May and June of 1984 were literally true, even if they are viewed as shrewdly calculated to evade Medicare regulations precluding reimbursemnt for chelation therapy. Thus, Ms. Flicker cited an alternative, but true, service designation.

Adding to the ambiguity of Medicare guidelines, and underscoring the fact that the evidence at trial was insufficient to support Dr. Bedi's convictions, is a recent administrative appeal decision of the Office of Hearings and Appeals for the Department of Health and Human Services. *See In re Bielby*, Docket No. 000-80-0070, (Decision filed February 6, 1991) [Appendix "D", *infra*]. In *Bielby*, the Office of Hearing and Appeals held that "for treatment of arteriosclerosis, chelation therapy was both reasonable, necessary, and entirely effective in this case," and "is considered to be a *covered service* for purpose of Part B Medicare reimbursement." [Appendix "D",

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[6]Dwayne Carter, the Medicare section supervisor for Blue Cross/Blue Shield, testified that a Medicare "NewsNote" dated July 1, 1984 defined chemotherapy as a treatment for malignant disease." Notwithstanding the fact that the "Newsnotes" was dated *after* the subject claims forms were submitted by Ms. Flicker in May and June of 1984, the record is devoid of any evidence that Dr. Bedi had ever seen the "Newsnote" or was aware of the definition. Moreover, former Medicare Professional Relations Representative Loraine Molinari testified at trial that the "Newsnotes" are strictly internal Medicare agency documents for adjustment of claims, and *never* distributed to physicians. In any event, malignant disease is defined in *Dorland's Medical Dictionary*, 27th Edition (Hardcort, Brace, Jenovic, Inc.) as "tending to become progressively worse and to result in death," without specific limitation to any particular disease.

infra, p. D-4 and D-5]. Moreover, the administrative appeals judge in *Bielby* concluded: "Thus, denial of reimbursement for these benefits [for chelation therapy], based upon the carrier guidelines, *violates due process*." [*Bielby*, *infra* at D-2].

The evidence presented below is insufficient to sustain Dr. Bedi's convictions for conspiracy to defraud Medicare and making a false, fictitious and fraudulent statement to a government agency. Those treatments and diagnoses designated by Ms. Flicker in May and June of 1984 on the Medicare claims forms were literally true and correct, even though they may have listed alternative treatments and codes, or were "calculated to evade" the non-coverage regulation concerning chelation therapy. The government had failed to show that the treatments and diagnoses on the subject claims forms were "literally false," and the record shows otherwise.

The 11th Circuit, in affirming Dr. Bedi's convictions, reached a decision in conflict with this Court's enunciations in *Bronston* and its above-noted progeny, which consistently emphasized that a literally true answer, even though unresponsive, misleading or "shrewdly calculated to evade" cannot form the predicate for a conviction for making a false statement. Moreover, since the recent administrative appeals decision of the Department of Health and Human Services has declared that chelation therapy is indeed a "covered service" in the case of treatment for arteriosclerosis, and non-coverage of such therapy by Medicare a denial of due process, [Appendix "D", *infra*], one cannot "conspire to defraud" the government to make a payment for which the government is obligated to pay anyway. In any event, this Court should grant certiorari to hear this cause in order to reiterate that a literally true answer cannot be the basis of a Section 286 and 287 conviction for making a false statement to a government agency, i.e. Medicare.

II. THE ACTS ALLEGED IN THE INDICTMENT DID NOT CONSTITUTE A VIOLATION OF THE STATUTES WHICH PETITIONER WAS CHARGED WITH VIOLATING, I.E. SUBMITTING "FALSE STATEMENTS" TO A GOVERNMENT AGENCY TO INDUCE MEDICARE REIMBURSEMENT FOR A "NON-COVERED SERVICE," AS ADMINISTRATIVE DECISION OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES DECLARES THAT SUCH SERVICES WERE INDEED "COVERED," AND IT IS A DENIAL OF DUE PROCESS FOR MEDICARE TO REFUSE REIMBURSEMENT UNDER SUCH CIRCUMSTANCES.

In *United States v Gimbel*, 830 F.2d 621, 624 (7th Cir., 1987), the court held:

> "In order to be valid, an indictment must allege that the defendant performed acts which, if proven, constituted a violation of the law that he or she is charged with violating. If the acts alleged in the indictment did not constitute a violation of the law that the defendant has been charged with violating, we must reverse any subsequent conviction based on that indictment. *See McNally v. United States*, 483 US 350, 107 S.Ct. 2875, 97 L.Ed.2d 292 (1987)."

In *McNally*, 483 US at 360, this Court emphasized with regard to fraud cases: "There are no constructive offenses; and before one can be punished, it must be shown that his case is plainly within the statute." "An indictment which fails to allege an essential element, however, cannot be saved by judicial construction and, their challenge for the first time on appeal, will not support a conviction for an offense which

requires the missing element." *United States v. Cloyd*, 819 F.2d 836, 839 (8th Cir., 1987).

Dr. Bedi was charged in this case with violations of 18 USC Sections 2, 286 and 287. As reflected in Exhibit "F" *infra*, those sections make it a crime to willfully aid, abet or induce the commission of an offense against the United States, to conspire to defraud a United States department or agency by obtaining, or aiding to obtain, the payment of any false, fictitious or fraudulent claim, and knowingly presenting a United States department or agency with a false, fictitious or fraudulent claim. Prior to trial Dr. Bedi moved to dismiss the indictment on the grounds that it "fail[ed] to state facts sufficient to constitute a crime or an offense against the United States. . .[or a] violation of any statutes that the United States is empowered to act.

The key portions of the indictment [Appendix "C", *infra*] allege that "*chelation was a non-covered service* under the Medicare program unless administered for" hypercalcemia, ventricular arrhythmias, or control of heart block secondary to digitalis toxicity. The indictment further alleges that chemotherapy was a covered service under the Medicare program "and *recognized* as a treatment for cancer."[7] [Appendix "C", *infra*]. More specifically, the indictment provides the following dispositve clauses:

> "2. It was further a part of the conspiracy that the defendant, SURINDAR S. BEDI, *knowing that chelation therapy was a non-covered Medicare service*, would and did cause Heart Helpers, Inc., to falsely bill the Medicare program by representing chelation therapy as

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[7]"Chemotherapy" is defined in *Stedman's Medical Dictionary* (25th Edition) as "Treatment of disease by means of chemical substances or drugs." In *Websters New Collegiate Dictionary* it is defined as "the use of chemical agents in the treatment or control of disease."

> cardiovascular chemotherapy on Medicare Health Insurance Claim Forms, which would then be sent off for payment under the provisions of the Medicare program.
>
> 3. It was further a part of the conspiracy that the defendant, SURINDAR S. BEDI, would and did cause Heart Helpers, Inc. to submit false claims to the Medicare program, such claims being false as they represented non-covered office services provided in conjunction with chelation therapy, as being covered office services provided in conjunction with cardiovascular chemotherapy."

The indictment woefully fails to allege a crime against the United States for several reasons:

First, by administrative decision [Appendix "D", *infra*], the Department of Health and Human Services recently held that "for treatment of arteriosclerosis, chelation therapy was both reasonable, necessary, and entirely effective," and "is considered to be a *covered service* for purposes of Part B Medicare reimbursement." [D 4-5, *infra*]. To deny reimbursement for chelation therapy, "based upon the carrier guidelines, violates due process." (*Bielby*, *infra* at Appendix "D", p. D-2).

Thus, the *key* allegation of the Government's fraud indictment, that chelation therapy in the case of treatment for arteriosclerosis is a "non-covered service," has been vitiated by administrative decision of the Department of Health and Human Services in *Beilby* [Appendix "D", *infra*].. Chelation therapy for treatment of arteriosclerosis is indeed a "covered service," and the indictment alleging otherwise fails to state an offense against the United States.

Second, the indictment does not state an offense against the United States since it fails to allege that cardiovascular chemotherapy is not a valid or covered treatment under these circumstances, or that cardiovascular chemotherapy was not actually administered by Dr. Bedi's medical clinic to the eleven patients for arteriosclerosis. In

fact, the Government never disputed the fact that these patients were actually administered cardiovascular chemotherapy, but rather maintained that is should have been labeled by its alternative "non-covered" designation, i.e. chelation therapy. The indictment's failure to allege that cardiovascular chemotherapy was never actually administered, or the intravenous treatments rendered to the eleven patients did not constitute cardiovascular chemotherapy, is fatal to the indictment.

The indictment gratuitously mentions that "chemotherapy" is "*recognized* as a treatment for cancer." [Appendix "C", *infra*, at p. C-2]. While certainly cancer is one of the many diseases for which chemotherapy may be administered,the indictment does not allege that cancer is the *only* disease for which chemotherapy can be administered and it obviously isn't. The allegation in the indictment that chemotherapy was a covered service, "and recognized as a treatment for cancer," is by no stretch of the imagination a sufficient allegation to establish that cardiovascular chemotherapy is a "literally false" designation for the intravenous treatments rendered to the eleven patients.

This Court should grant certiorari to hear this case, to assert that subsequent administrative decision of a government agency will supersede ambiguous regulatory guidelines.

CONCLUSION

For all of the foregoing reasons, arguments and authorities, it is respectfully submited that the Writ of Certiorari be granted.

Respectfully submitted,

SAMUEL R. MANDELBAUM,
ESQUIRE
(Member of U.S. Supreme Court Bar)
SMITH & WILLIAMS, P.A.
712 South Oregon Avenue
Tampa, Florida 33606
(813) 253-5400

ATTORNEYS FOR PETITIONER

Dated: June 14, 1991

APPENDIX

APPENDIX A

UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF FLORIDA

Case Number 89-93-Cr-T-13(08)

B. Anderson Mitcham
Attorney for Defendant

UNITED STATES OF AMERICA

vs.

SURINDAR S. BEDI
2207 Belchery Court
Clearwater, Florida 34624

JUDGMENT IN A CRIMINAL CASE

THE DEFENDANT ENTERED A PLEA OF:
[___ guilty ____ nolo contendere] as to count(s)_____, and
[X__ not guilty as to count(s)_____one to twenty_____.

THERE WAS A:
[___ finding X__ verdict] of guilty as to count(s) one to twenty_____.

THERE WAS A:
[___ finding___ verdict] of not guilty as to count(s)_____.
____ judgment of acquittal as to count(s)_____.
The defendant is acquitted and discharged s to this/these counts.

THE DEFENDANT IS CONVICTED OF THE OFFENSE(S) OF:
Count 1-conspiracy to defraud government with respect to claims in violation of Title 18, U.S.C., Section 286

Counts 2-20-false, fictitious or fraudulent claims in violation of Title 18, U.S.C., Section 287.

IT IS THE JUDGMENT OF THIS COURT THAT: the defendant be committed to the custody of the Bureau of Prisons or its authorized representative for a period of imprisonment of five (5) years as to each of counts one thru twenty. Sentences imposed are to be served CONCURRENTLY with each other. IT IS FURTHER ORDERED that the defendant, within one year after he begins serving his sentence, make restitution in the amount of $24,115.72 to: Department of Health and Human Services, Healthcare Financing Administration, Medicare Part B., Attn: Special Agent Kyle R. Ford, 2189 Cleveland St., Suite 227, Clearwater, Florida 34625.

in addition to any conditions of probation imposed above, IT IS ORDERED that the conditions of probation set out on the reverse of this judgment are imposed.

CONDITIONS OF PROBATION

Where probation has been ordered the defendant shall:

(1) refrain from violation of any law (federal, state, and local) and get in touch immediately with your probation officer if arrested or questioned by a law-enforcement officer;

(2) associate only with law-abiding persons and maintain reasonable hours;

(3) work regularly at a lawful occupation and report your legal dependents, if any, to the best of your ability. (When out of work notify your probation officer at once, and consult him prior to job changes);

(4) not leave the judicial district without permission of the probation officer;

(5) notify your probation officer immediately of any changes in your place of residence;

(6) follow the probation officer's instructions and report as directed.

The court may change the conditions of probation, reduce or extend the period of probation, and at nay time during the probation period or within the maximum probation period of 5 years permitted by law, may issue a warrant and revoke probation for a violation occurring during the probation period.

IT IS FURTHER ORDERED that the defendant shall pay a total special assessment of $1,000.00 pursuant to Title 18, U.S.C., Section 5013 for count(s): one thru twenty as follows:

IT IS FURTHER ORDERED that counts _____ are DISMISSED on the motion of the United States.

IT IS FURTHER ORDERED that the defendant shall pay to the United States attorney for this district any amount imposed as a fine, restitution or special assessment. The defendant shall pay to the clerk of the court any amount imposed as a cost of prosecution. Until all fines, restitution, special assessments and costs are fully paid, the defendant shall immediately notify the United States attorney for this district of any change in name and address.

IT IS FURTHER ORDERED that the clerk of the court deliver a certified copy of this judgment to the United States marshal of this district.

_____ The Court orders commitment to the custody of the Attorney General and recommends:

April 12, 1990
Date of Imposition of Sentence

_____
Signature of Judicial Officer

BEN KRENTZMAN, SENIOR U.S. DISTRICT JUDGE
Name and Title of Judicial Officer

April 13, 1990
Date

RETURN

I have executed this Judgment as follows:

_____
_____
_____

Defendant delivered on _____ to _____
at _____, the institution designated

by the Attorney General, with a certified copy of this Judgment in a Criminal Case.

_____
United States Marshal

By _____
Deputy Marshal

APPENDIX B

IN THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

NO. 90-3346
NON-ARGUMENT CALENDAR

D.C. DOCKET NO. 89-93-CR-T-13B

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

vs.

SURINDAR S. BEDI,

Defendant-Appellant.

APPEAL FROM THE UNTIED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF FLORIDA

(March 18, 1991)

Before TJOFLAT, Chief Judge, JOHNSON and DUBINA, Circuit Judges.

PER CURIAM:

AFFIRMED. *See* 11th Cir. r. 36-1.

APPENDIX C

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

CASE NO 89-93-Cr-T-13 B

UNITED STATES OF AMERICA

v.

SURINDAR S. BEDI

FILED
Clerk of the
Circuit Court
1989 May 11 PM
4:33
MIDDLE
DISTRICT OF
FLORIDA
TAMPA,
FLORIDA

INDICTMENT

THE GRAND JURY CHARGES:

COUNT I

A. INTRODUCTION

AT ALL TIME MATERIAL TO THIS INDICTMENT:

1. The Medicare program, as established by Act of the United States Congress, existed as a health insurance program for eligible aged, blind, and disabled individuals. Part B of the Medicare program was operating to providing reimbursement for physician services, medical services and supplies, and out-patient services to qualified recipients.

2. The Health Care Financing Administration (HCFA) of the United States Department of Health and Human Services (DHHS) was the governmental body responsible for administering the Medicare program.

3. Within the State of Florida, Blue Cross and Blue Shield of Florida, Inc., was under contract with HCFA and DHHS to oversee part B of the Medicare program.

4. HCFA regulations provided that in order for a medical service to be reimbursable under the Medicare program, the service must (a) be a covered service, (b) be medically necessary, and (c) have actually been performed.

5. Chelation therapy was a non-covered service under the Medicare program unless administered for (a) emergency treatment of hypercalcemia, (b) control of ventricular arrhythmias, or (c) control of heart block secondary to digitalis toxicity.

6. Chemotherapy was a covered service under the Medicare program, and recognized as a treatment for cancer.

7. Claims for reimbursement for covered Medicare services within the State of Florida were submitted on a Medicare Health Insurance Claim Form to Blue Cross and Blue Shield of Florida, who, on behalf of HCFA and DHHS, would pay the claim.

8. Surindar S. Bedi was the owner and executive director of Heart Helpers, Inc., a medical clinic in Zephyrhills, Florida.

B. THE CONSPIRACY

From on or about March 13, 1984, through on or about June 30, 1984, in the Middle District of Florida, the Defendant,

SURINDAR S. BEDI,

Heart Helpers, Inc., not indicted herein, and others known and unknown to the grand jury, did knowingly and willfully enter into an agreement, combination, and conspiracy with each other to defraud the United States and the Department of Health and Human Services (DHHS), a department of the United States, by obtaining and aiding to obtain payment of false, fictitious and fraudulent claims.

C. MANNER AND MEANS

1. It was a part of the conspiracy that the defendant, SURINDAR S. BEDI, would and did operate Heart Helpers, Inc. as a clinic providing chelation therapy.

2. It was further a part of the conspiracy that the defendant, SURINDAR S. BEDI, knowing that chelation therapy was a non-covered Medicare service, would and did cause Heart Helpers, Inc., to falsely bill the Medicare program by representing chelation therapy as cardiovascular chemotherapy on Medicare Health Insurance Claim Forms, which would then be sent off for payment under the provisions of the Medicare program.

3. It was further a part of the conspiracy that the defendant, SURINDAR S. BEDI, would and did cause Heart Helpers, Inc. to submit false claims to the Medicare program, such claims being false as they represented non-covered office services provided in conjunction with chelation therapy, as being covered office services provided in conjunction with cardiovascular chemotherapy.

D. OVERT ACTS

To effect the objects of the conspiracy, the following overt acts were committed in the Middle District of Florida, and elsewhere, among which are the following:

1. On or about the dates listed below, in the Middle District of Florida, the Defendant, SURINDAR S. BEDI, caused Heart Helpers, Inc. to file false and fraudulent claims against the United States as follows:

Overt Act	Approximate Date of Claim	Patient	Claimed Service Provided	Actual Service Provided
1.	05/02/84	Ethel Watson	Cardiovascular Chemotherapy	Chelation Therapy
2.	03/31/84	George Davis	Cardiovascular Chemotherapy	Chelation Therapy

3.	05/02/84	George Davis	Cardiovascular Chemotherapy	Chelation Therapy
4.	03/31/84	Wesley Goodman	Cardiovascular Chemotherapy	Chelation Therapy
5.	05/02/84	Wesley Goodman	Cardiovascular Chemotherapy	Chelation Therapy
6.	03/31/84	Frederick Wright	Cardiovascular Chemotherapy	Chelation Therapy
7.	05/02/84	Frederick Wright	Cardiovascular Chemotherapy	Chelation Therapy
8.	03/31/84	Lennie May Green	Cardiovascular Chemotherapy	Chelation Therapy
9.	05/02/84	Lennie May Green	Cardiovascular Chemotherapy	Chelation Therapy
10.	05/02/84	Frank Prelesnick	Cardiovascular Chemotherapy	Chelation Therapy
11.	04/23/84	Fred P. Atteberry	Cardiovascular Chemotherapy	Chelation Therapy
12.	05/02/84	Fred P. Atteberry	Cardiovascular Chemotherapy	Chelation Therapy

The acts described in Counts Two through Twenty of this Indictment are hereby incorporated by reference and realleged as Overt Acts Thirteen through Thirty-One of this Count.

All in violation of Title 18, United States Code, Section 286.

COUNTS TWO THROUGH TWENTY

FALSE CLAIMS

On or about the below listed dates, in the Middle District of Florida, the defendant,

SURINDAR S. BEDI,

did knowingly make and cause Heart Helpers, Inc., to make to Blue Cross and Blue Shield of Florida, Inc., an agent of the United States Department of Health and Human Services (DHHS), a department of the United States, in that defendant represented and caused to be represented in Health Insurance Claim Forms submitted under the Medicare program, that Heart Helpers, Inc., had provided certain patients listed below with chemotherapy, a service covered by the Medicare program, whereas, as the defendant then and there well knew, such claims were false and fraudulent as Heart Helpers, Inc., had actually provided these patients with chelation therapy, a non-covered service under the Medicare program.

COUNT	APPROXIMATE DATE OF CLAIM	PATIENT ON WHOSE BEHALF CLAIM WAS SUBMITTED
2	May 30, 1984	Ethel Watson
3	June 28, 1984	Ether Watson
4	May 31, 1984	Josephine Bernal
5	June 28, 1984	Josephine Bernal
6	May 30, 1984	George Davis
7	June 28, 1984	George Davis
8	May 30, 1984	Wesley Goodman
9	May 30, 1984	George C. Miller
10	June 28, 1984	George C. Miller
11	May 30, 1984	Frederick Wright
12	June 28, 1984	Frederick Wright
13	May 30, 1984	Florence Pressick
14	May 30, 1984	Lennie Mae Green
15	June 28, 1984	Lennie Mae Green
16	May 30, 1984	Frank Prelesnick
17	June 28, 1984	Frank Prelesnick
18	May 30, 1984	Fred P. Atteberry
19	June 28, 1984	Fred P. Atteberry
20	June 28, 1984	Kenneth Axford

All in violation of Title 18, United States Code, Sections 287 and 2.

A TRUE BILL

_____
FOREMAN

ROBERT W. GENZMAN
United States Attorney

By: /s/ James L. Powers
JAMES L. POWERS
Assistant United States Attorney
Chief, Fraud Section

By: /s/ Todd Foster
TODD FOSTER
Assistant United States Attorney

APPENDIX D

**NOTE TO PROCESSING CENTER:
FURTHER ACTION NECESSARY**

**DEPARTMENT OF
HEALTH AND HUMAN SERVICES**
Social Security Administration
OFFICE OF HEARINGS AND APPEALS

DECISION

IN THE CASE OF:	CLAIM FOR:
George Bielby (Claimant)	Medicare Part B Benefit
(Wage Earner)	000-80-0070 (Social Security Number)

This case is before the undersigned Administrative Law Judge on a timely request for hearing filed by the claimant on July 2, 1990. The case came on for hearing on December 5, 1990, in Denver, Colorado. The claimant appeared personally at the hearing, and was represented by David Bielby, his son; (although thoroughly advised of his right to attorney representation in the notice of hearing and by separate attachment). The issue at the hearing was whether payment may be made under Part B of Title XVIII of the Social Security Act for the care/services rendered during the period December 5, 1988 through July 20, 1989. After careful consideration of the entire evidence of record, the undersigned has found that payment will be made for the services in question.

EVALUATION OF THE EVIDENCE

Medical records reveal that the claimant has a long history of coronary artery disease, having suffered several heart attacks. In November 1988, his condition deteriorated and he was admitted to the hospital for diagnostic testing. Cardiac catheterization revealed poor left ventricular function with a large akinetic (not moving) area over the anterior apical region,

with ejection fractions of approximately 36 percent, an aneurysm, severe triple vessel coronary artery disease with two to three plus mitral insufficiency and evaluated pulmonary pressures. Because of the nature of the atherosclerotic plaques, as well as his general medical condition, the claimant was not a good surgical candidate. There was an operative risk of at least 15 percent, and it was decided that the claimant would not benefit from any bypass surgery, even if he survived it (Exhibit 16). The claimant was discharged on medication and he testified at the hearing that he was essentially "sent home to die".

After discharge, the claimant was extremely functionally limited, having a very short walking tolerance and experiencing almost constant anginal pain. The claimant was referred to Dr. Fish, a Diplomat of the American Board of Chelation Therapy. Chelation therapy is used to restore blood flow without surgery to victims of atherosclerosis. The therapy involves intravenous infusion of a prescription medicine called Ethylene Diamene Tetra-acetic Acid (EDTA). This substance removes undesirable metals from the body and improves calcium and cholesterol metabolism. Chelation therapy is now believed by many scientists to be helpful in the treatment of atherosclerosis, cancer, diabetes, and other diseases of aging. Since Chelation therapy has not been approved by the FDA, use of EDTA is considered experimental and was denied coverage for reimbursement of Medicare Part B benefits in this case.

42 CFR 405.502(c) provides, in pertinent part, that the carrier must exercise judgment based on special factors that may exist in individual cases so that determinations of reasonable charge are realistic and equitable. Due process of law requires that a claimant have an opportunity to offer evidence that, in this case, Chelation therapy is reasonable and necessary for his care. Thus, denial of reimbursement for these benefits, based upon the carrier guidelines, violates due process. Due process also requires a detached and neutral decision-maker. The undersigned approaches this case fully prepared to exercise the judgment outlined in the regulations, and is not bound by the rigid interpretations set forth in the Medicare Carrier's Manual.

In this case, the claimant turned to Chelation therapy in a "last ditch effort" to preserve his life. Standard accepted medical practice had failed to improve his condition, and in fact, his condition had worsened to the point that he was facing death. There is no doubt that it was reasonable for the claimant to seek relief from his constant pain, without concern for whether the charges would be covered by Medicare. The necessity of the therapy has also been demonstrated. The claimant was not expected to survive his rapidly progressing coronary artery disease, nor was he expected to survive or be helped by surgery. According to the literature regarding Chelation therapy which was submitted by the claimant (Exhibit 20), Chelation therapy promotes health by correcting the major underlying cause of arterial blockage. Blood flow is increased as the arterial plaques shrink. In Mr. Bielby's case, the improvement in his general health was dramatic. When he first sought treatment from Dr. Fish in November 1988, he exhibited marked fatigue, constant chest pain, shortness of breath, leg cramps, and edema of the feet and ankles. He was unable to sleep lying flat in bed because of shortness of breath and had to sleep sitting up. His wife slept near him on a couch each night for fear of leaving him alone. After only three treatments, the claimant's breathing, fatigue, and chest pain all changed for the better. His blood pressure was lowered to 138/68. No edema was present. He now has no shortness of breath or chest pain, he walks every day without leg cramps, and is able to go fishing at 9200 feet elevation. His energy level is greatly increased, his mental confusion has cleared, and his libido has increased. Dr. Kucinski, a cardiologist, submitted a letter in August 1989 stating that while he was not ordinarily a strong advocate of this type of this therapy and had viewed it in the past "with a raised eyebrow", he had to admit that Mr. Bielby had exhibited "notable and measurable progress" since the treatments had been initiated. This doctor noted the claimant's better condition mentally and his marked increase in the general quality of his life. Dr. Kucinski recommended that similar patients "who had no other option available" should explore the treatment possibilities related to Chelation therapy (Exhibit 17).

The undersigned observed the claimant at the hearing and was strongly impressed by his vitality and apparent recovery. He

appeared to move easily without any obvious indicators of pain or shortness of breath; he answered questions alertly and participated in the course of the hearing without any signs of diminished mentation; and he simply appeared to be the picture of health compared to the description of his condition in November 1988, before the Chelation therapy. The claimant submitted a great deal of evidence providing information about Chelation therapy and the claims that are made regarding it's ability to practically reverse the aging process. This claimant did not appear to be a person who was seeking any "fountain of youth", but was a person who was desperately searching for a way to live. It is clear to the undersigned that this claimant made a remarkable recovery after undergoing Chelation therapy. The therapy was both reasonable and necessary. The cost of Chelation therapy is extremely small when compared to the bill that Medicare would have received if this claimant had been subjected to surgery and the possibilities for complication and death which would have insued. The amount in controversy in this case ($2,100) is miniscule compared to today's costs for coronary bypass surgery. Exercising the discretion and good judgment described in the regulations, the undersigned therefore directs the Medicare carrier to reprocess Mr. Bielby's claim and calculate the reimbursable benefits based upon a decision that the Chelation therapy in this case is a covered service.

FINDINGS

After careful consideration of all of the evidence of record, the undersigned has made the following findings:

1. During the period December 5, 1988 through July 20, 1989, the claimant underwent Chelation therapy.

2. Although not approved by the FDA for treatment of atherosclerosis, Chelation therapy was both reasonable, necessary, and entirely effective in this case.

3. The claimant's condition drastically improved as a direct result of the Chelation therapy.

4. Exercising good judgment, the undersigned finds that the Chelation therapy in this case is considered to be a covered service for purposes of Part B Medicare reimbursement.

DECISION

It is the decision of the undersigned that the Chelation therapy at issue in this case is to be considered a covered service and that the Medicare Carrier will recalculate the reimbursable benefit in this claim pursuant to such finding; and appropriately reimburse the claimant.

/s/Fredrick B. Strothman
FREDRICK B. STROTHMAN

February 6, 1991
DATE

DEPARTMENT OF
HEALTH & HUMAN
SERVICES

Social Security Administration
Office of Hearings and Appeals
Region VIII
Federal Building
Suite 751 1244 Speer Blvd.
Denver, CO 80204-3500
Telephone: (303) 844-5800
(FTS) 564-5800

CERTIFICATION OF THE ADMINISTRATIVE LAW JUDGE DECISION

I hereby certify that the attached decision is the true signature of the Administrative Law Judge presiding on the case of George Bielby.

/s/Linda Hardin
Linda Hardin
Hearing Assistant

Date: May 9, 1991

APPENDIX E

CPT CODE MANUAL

Chemotherapy Injections

Procedures 96500-96549 are independent of the patient's office visit. Either may occur independently from the other on any given day, or they may occur sequentially on the same day. Intravenous chemotherapy injections are administered by a physician or by a qualified assistant under supervision of the physician.

Regional (isolation) chemotherapy perfusion should be reported using existing codes describing complex arterial chemotherapy. Placement of the catheter should be reported using the appropriate code from the cardiovascular surgery section. Adjunctive procedures such as lymph node dissection, wide local excision and skin grafts should also be identified separately.

96500 Chemotherapy injection, intravenous, single premised agent, administered by qualified assistant under supervision of physician or by physician; by push technique

96501 by infusion technique

96504 Chemotherapy injection, intravenous, multiple premixed agents, administered by qualified assistant under supervision of physician or by physician; by push technique

96505 by infusion technique

APPENDIX F

STATUTES

18 USC § 2.Principals

(a) Whoever commits an offense against the United States or aids, abets, counsels, commands, induces or procures its commission, is punishable as a principal.

(b) Whoever willfully causes an act to be done which if directly performed by him or another would be an offense against the United States, is punishable as a principal.

18 USC § 286 Conspiracy to defraud the Government with respect to claims

Whoever enters into any agreement, combination, or conspiracy to defraud the United States, or any department or agency thereof, by obtaining or aiding to obtain the payment or allowance of any false, fictitious or fraudulent claim, shall be fined not more than $10,000 or imprisoned not more than ten years, or both.

18 USC § 287. False, fictitious or fraudulent claims

Whoever makes or presents to any person or officer in the civil, military, or naval service of the United States, or to any department or agency thereof, any claim upon or against the United States, or any department or agency thereof, knowing such claim to be false, fictitious, or fraudulent, shall be imprisoned not more than five years and shall be subject to a fine in the amount provided in this title.